

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

-----	X	
	:	
RISING PHARMA HOLDINGS, INC. and	:	
APPCO PHARMA LLC,	:	Civil Action No. 2:24-cv-1435
	:	
Plaintiffs,	:	
	:	
-against-	:	
	:	
COSETTE PHARMACEUTICALS, INC.;	:	
FIS NORTH AMERICA, INC.; AND	:	
FABBRICA ITALIANA SINTETICI S.P.A.	:	
	:	
Defendants.	:	
	:	
	:	
-----	X	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Rising Pharma Holdings, Inc. (“Rising”) and Appco Pharma LLC (“Appco”) (together, “Plaintiffs”) bring this action to stop and remedy ongoing unlawful conduct by Cosette Pharmaceuticals, Inc. (“Cosette”); FIS North America, Inc. (“FIS N.A.”); and Fabbrica Italiana Sintetici S.p.A. (“FIS VI” and together with FIS N.A., “FIS”) (together with Cosette, “Defendants”). Plaintiffs seek damages and injunctive relief under federal and state laws, and demand a trial by jury.

INTRODUCTION

1. This is an action under the Sherman Act, New Jersey Antitrust Act, and other common law causes of action arising out of Defendants’ anticompetitive conduct to delay and prevent generic competition to Cosette’s pharmaceutical product Clomid® (clomiphene citrate tablets). For more than 50 years, clomiphene citrate tablets have been an important drug to many

women who struggle with infertility, and without it many would lack an affordable and safe way to successfully achieve pregnancy.

2. Clomid[®] is not a new or innovative drug. In fact, in 1965, a new drug application for clomiphene citrate was filed with the U.S. Food and Drug Administration (“FDA”). The FDA approved clomiphene citrate tablets in 1967, when it first became available by prescription in the United States. But despite the fact that the drug has been on the market for decades, there currently is no generic competition for Clomid[®]. This was not always the case. In 1999, Par Pharmaceutical, Inc. (“Par”) received FDA approval to launch a generic clomiphene citrate product, and the product continued to be sold as a generic pharmaceutical until 2022.

3. That is when Cosette embarked on a strategy to acquire the generic clomiphene citrate product and then raise the price of the rebranded generic (as Clomid[®]) by seeking to control the supply of active pharmaceutical ingredients (“API”) available on the market.

4. First, as part of its scheme, in September 2022, Cosette obtained from Par the right to market and sell the only generic clomiphene citrate tablets on the market. But a generic product that had been on the market for more than 50 years could not garner a premium price.

5. Second, Cosette thus conceived of the idea to “rebrand” the drug “Clomid” and announced on October 7, 2022, that Clomid[™] was available for sale. On November 8, 2022, Cosette obtained a registered trademark from the U.S. Patent & Trademark Office. This product was neither new nor novel but simply the old generic clomiphene citrate tablets restyled in branded packaging. So, with its new trademark rights in hand, Cosette began selling the old generic clomiphene citrate as branded “Clomid[®].”

6. Third, without any apparent increase in costs and no change to the product, Cosette increased the price of Clomid[®] to retail pharmacies, wholesalers, insurers, and government agencies by more than 1,000 percent.

7. But Cosette's scheme was not yet complete. To accomplish its objective of being able to maintain monopoly prices for Clomid[®] over time, Cosette needed to ensure that no other generic competitor could come to market. Cosette accomplished this by controlling access to the API.

8. API is the active ingredient that provides the beneficial health effect used in combination with inactive ingredients to manufacture the finished dose pharmaceutical product and is essential for the manufacture of pharmaceutical products. By obtaining exclusive rights to API, and denying its competitors access to API, Cosette would bar generic competitors for clomiphene citrate tablets, making it easier for Cosette to raise and maintain substantially higher prices.

9. For the last several years, Appco had been researching and developing generic clomiphene citrate tablets to launch in the U.S. market. During this time, Appco obtained API from FIS and otherwise depended on FIS for technical support in order to obtain approval for Appco's Abbreviated New Drug Application ("ANDA") from the FDA.

10. To sell API in the United States, the API supplier needs to submit a Drug Master File ("DMF") to the FDA, which provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API. To obtain FDA approval to market and sell the drug, a drug developer must include in its ANDA filing the API manufacturer's DMF.

11. FIS agreed to provide API to Appco in connection with product development and the manufacture of exhibit or submission batches that accompany the filing of an ANDA for regulatory approval to the FDA. Additionally, in connection with Appco's planned ANDA filing, on or about September 19, 2022, FIS provided a Letter of Authorization ("LOA") to the FDA granting Appco a "right of reference" to its DMF. This means that the FDA is informed that Appco's product utilizes FDA-approved API from a particular source, which enables the FDA to rely on information regarding FIS's DMF in reviewing Appco's ANDA application. For all of those reasons, FIS knew that Appco was relying on FIS's API and its approved DMF to secure FDA approval for its clomiphene citrate product.

12. The FDA can grant Competitive Generic Therapy ("CGT") status to genericized products that lack generic competition upon an application by a drug developer. This status provides 180-day exclusivity period to the first drug developer to secure FDA approval for the CGT designated drug and commercially markets such drug within 75 calendar days after approval. During the exclusivity period, no other generics can receive approval to market and sell a bioequivalent product. Due to the lack of generic competition in the U.S. market for clomiphene citrate tablets, the FDA granted Appco's application for a CGT designation for clomiphene citrate tablets on November 19, 2021. The government thus recognized the importance of Plaintiffs' launch of a generic competitor to Clomid®.

13. On or about March 9, 2023, Appco submitted an ANDA to the FDA to obtain the right to market and sell clomiphene citrate tablets. The FDA provided an approval goal date of January 9, 2024.

14. On December 30, 2021, Appco entered into an exclusive licensing agreement with Rising authorizing Rising to market and sell this new product once approved by the FDA. Rising

agreed to pay fifty percent (50%) of the development costs of the product making it a co-developer of the product. But Rising's ability to launch what it expected to be a newly approved generic product has been prevented by Cosette's anticompetitive scheme and Defendants' unlawful agreement.

15. Appco representatives met with FIS in January of 2023 at an industry conference. At that time, FIS did not indicate any issue or problem with supplying its API to Appco knowing it was in support of Appco's efforts to bring a generic clomiphene citrate tablet to market, as acknowledge in FIS's LOA.

16. Upon information and belief, in or around February 2023, Defendants entered into a long-term, exclusive agreement whereby Cosette would purchase all of FIS's available clomiphene citrate API and FIS would agree not to otherwise sell to Appco any API until at least 2026 or 2027, if not later. In exchange for this arrangement, FIS indicated that Cosette provided FIS with a profit-share in sales of Clomid® or some other financial incentive to induce FIS to participate in its anticompetitive strategy. Around this time, FIS informed Appco that it had no "product plan" for 2023. Thereafter, FIS refused to continue any efforts to support Appco's ANDA with the FDA, including providing the regulatory, documentary, and testing assistance it previously agreed to and had provided.

17. The purpose and effect of this exclusive dealing arrangement was to prevent Rising from launching generic clomiphene citrate tablets in competition with Cosette's Clomid®. Without competition from Plaintiffs, Cosette could command supracompetitive prices for the only clomiphene citrate product on the market.

18. Cosette's exclusive arrangement with FIS cannot be justified by any legitimate business purpose and can be explained only as part of an anticompetitive strategy to prevent and

delay competition to Clomid[®] in order to obtain prices well above competitive levels. On information and belief, Cosette purchased more clomiphene citrate API from FIS than can be used to supply the entire U.S. market for clomiphene citrate.

19. FIS's decision not to supply Plaintiffs with clomiphene citrate for commercial launch and to withdraw assistance in securing the approval of the ANDA is contrary to normal business practices.

20. Defendants' exclusive dealing arrangement foreclosed the U.S. market from supply of clomiphene citrate API. Despite Plaintiffs' best efforts to find an alternative API supplier, FIS is the only clomiphene citrate API supplier in the U.S. market with the capacity to support the launch of a generic clomiphene citrate product or even provide sufficient support to secure approval of the ANDA. Yet, FIS refuses to sell clomiphene citrate API to Plaintiffs in amounts to support a commercial launch for years to come or even provide other support and smaller quantities of API to ensure Appco's ANDA will be approved by the FDA.

21. As a result of Defendants' conduct and Cosette's substantial and unprecedented price increases for Clomid[®], not only have Plaintiffs been harmed, but purchasers, including retail pharmacies, wholesalers, insurers, and government agencies, have paid substantially higher prices and, unless Defendants' conduct is enjoined, will continue to pay higher prices. Plaintiffs seek an order requiring Defendants to cease their unlawful conduct and recover compensatory and treble damages, and an award of Plaintiffs' costs and attorneys' fees.

PARTIES

22. Plaintiff Rising Pharma Holdings, Inc. is a company organized and existing under the laws of Delaware with its principal place of business in Allendale, New Jersey.

23. Plaintiff Appco Pharma LLC is a company organized and existing under the laws of Delaware with its principal place of business in Piscataway, New Jersey.

24. On information and belief, Defendant Cosette Pharmaceuticals, Inc. is a company organized and existing under the laws of Delaware with its principal place of business in Bridgewater, New Jersey.

25. On information and belief, Fabbbrica Italiana Sintetici S.p.A. (“FIS VI”) is a company organized and existing under the laws of Italy with its principal place of business in Vicenza, Italy specializing in the production of chemical products for the pharmaceutical industry.

26. On information and belief, Defendant FIS North America, Inc. (“FIS N.A.”) is a company organized and existing under the laws of Delaware with its principal place of business in Hackensack, New Jersey and acted as FIS VI’s agent for the North American market.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

27. This Court has subject matter jurisdiction pursuant to Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and 28 U.S.C. §§ 1331 and 1337.

28. This Court’s exercise of supplemental jurisdiction over Plaintiffs’ state law claims – New Jersey Antitrust Act § 56:9–4 and § 56:9–3 as well as state and common laws – would avoid unnecessary duplication and multiplicity of actions and should be exercised in the interests of judicial economy, convenience, and fairness.

29. The actions complained of have occurred in and have a substantial effect on interstate commerce. Specifically, Defendants are engaged in interstate commerce and in activities substantially affecting interstate commerce. Cosette purchases clomiphene citrate API in interstate commerce; FIS sells clomiphene citrate API in interstate commerce; and Defendants’ products are marketed and sold in all states and territories in the U.S. Drug wholesalers and retailers and, ultimately, patients across the country purchase Cosette’s drugs, including Clomid®, which include FIS-supplied API.

30. Venue is proper in this District pursuant to Section 12 of the Clayton Act, 15 U.S.C. §§15 and 22, and 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to the claims occurred in this District; a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District; and one or more of Defendants reside, are licensed to do business in, are doing business in, had agents in, or are found or transact business in this District.

31. This Court has personal jurisdiction over Defendants because each has the requisite constitutional contacts with the State of New Jersey due to their domicile, the extent of their business transactions within New Jersey, their contracts to supply goods and services in New Jersey, their solicitation of business in New Jersey, and/or commission of unlawful acts as alleged herein within the State of New Jersey. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

STATEMENT OF FACTS

I. STATUTORY AND REGULATORY BACKGROUND

A. Hatch-Waxman Framework

32. The Federal Food, Drug and Cosmetic Act (“FD&C Act”), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the “Hatch-Waxman Act,” requires approval by the FDA before a company may market or sell a branded or generic pharmaceutical product in the United States. The overarching purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies’ incentives to develop new drugs with the public

interest in access to lower-cost generic drugs through the creation of a carefully calibrated regulatory framework.

33. To achieve the first goal, the Hatch-Waxman Act provides for multiple types of exclusivities for brand drugs. For example, the Hatch-Waxman Act provides for a five-year exclusivity period for “new chemical entities” (“NCE”), i.e., where the API has not been previously approved for any other drug. 21 U.S.C. § 355(c)(3)(E)(ii). Generic developers are permitted to file their ANDAs one year before the expiration of the NCE exclusivity.

34. To achieve the second goal, the Hatch-Waxman Act creates a procedure for generic developers to file ANDAs with the FDA. An ANDA filer need not conduct full clinical trials, as is required for a New Drug Application (“NDA”). Instead, an ANDA filer has to show only that its drug is bioequivalent to the reference listed drug (“RLD”), typically the brand drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the RLD. If an ANDA meets the FDA’s requirements for establishing that the generic product is bioequivalent to the RLD, then the FDA will give the ANDA product an “AB” rating which indicates that the ANDA product is therapeutically equivalent to the RLD.

35. Under the Hatch-Waxman Act, NDA holders are required to identify all patents covering the brand drug and such patents’ expiration dates in an FDA publication referred to as the “Orange Book.” 21 U.S.C. § 355(b)(1) and (c)(2). If an ANDA applicant seeks FDA approval to sell a generic drug where there are no patents (Paragraph I) or following the expiration of the patents listed in the Orange Book as covering the drug (Paragraph II), the ANDA must contain a certification that there are no relevant patents covering the drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I), (II).

36. The ANDA applicant may sell the generic product in the United States. only upon receiving final approval from the FDA. Once the ANDA receives final approval, the ANDA applicant may immediately launch its generic drug regardless of the progress of any patent litigation.

B. Competitive Generic Therapy Designation

37. The FD&C Act, as amended by the FDA Federal Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005 (2017), enables the FDA to designate a drug with “inadequate generic competition” as a CGT. The FDA defines “inadequate generic competition” to mean that there is not more than one approved drug in the active section of the Orange Book. *Id.* A drug developer can request that the FDA designate a drug as a CGT at any time prior to the submission of an original ANDA or concurrently with such a submission.

38. Applicants for drugs that have been designated as CGTs can request expedited development and review of their ANDAs. The FDA will consider the complexity of developing an application for the specific drug subject to the request, the potential health impact of the product, and the impact on FDA resources and other existing workload commitments when it determines whether to grant a request for expedited development.

39. To incentivize generic drug companies to obtain approval and market drugs for which there is inadequate generic competition, sections 505(j)(5)(B)(v) and 505(j)(5)(D)(iv) of the FD&C Act grant successful CGT drug developers 180-day marketing exclusivity periods upon the commercial launch of their products, during which time other ANDAs for the CGT ANDA’s referenced drug are not granted.

40. An ANDA for a drug that has been designated as a CGT is granted the 180-day marketing exclusivity period when the ANDA is approved as long as (1) there were no unexpired patents or exclusivities listed in the Orange Book for the relevant RLD at the time the applicant

submitted the original ANDA to the agency and (2) the ANDA applicant commercially markets its CGT product within 75 calendar days after the approval of the ANDA.

C. Benefits of Generic Competition

41. Generic drugs are usually sold at significantly cheaper prices than their brand counterparts. The first generic drug that enters the market generally is priced at a significant discount to the brand product. As additional generic drugs enter the market, generic drug prices may fall to as low as five percent of the brand drug's price. A 2017 study commissioned by the Association for Accessible Medicines ("AAM") found that while brand drug prices generally increased by over 200 percent between 2008 and 2016, generic drug prices generally decreased by approximately 75 percent during this period.

42. Because generic drugs are typically priced substantially lower than the brand drug price, in a competitive market they typically take substantial market share from the corresponding brand drugs upon launch, with the proportion of patients and payers switching to the generic drug increasing over time. The increase in the volume that generic drugs take from their corresponding brand drugs means that generic drugs provide increased cost savings over time.

43. Generic drug competition generates large savings for consumers and federal, state, and private payors such as health plans and insurers. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52 percent in their daily medication costs. More recently, a 2023 AAM study found that generic drugs (including generics of biologics known as biosimilars) generated savings of \$2.9 trillion for the U.S. health care system between 2013 and 2022.

44. Generic savings have steadily increased from \$8-10 billion in 1994, as found by a 1998 Congressional Budget Office Report, to \$408 billion in savings from generic drugs and biosimilars in 2022, as found by the 2023 AAM study. The 2023 AAM study also cites to industry

data showing that generic drugs and biosimilars account for 90 percent of prescriptions, but less than 18 percent of costs. Similarly, the 2016 Report to Congress on “Prescription Drugs: Innovation, Spending, and Patient Access” from the U.S. Department of Health and Human Services unequivocally states: “Generic drugs account for the majority of dispensed prescriptions, but a relatively small percentage of spending.”¹

D. Supply and Use of API in Drug Products

45. Brand and generic developers ordinarily purchase API for use in manufacturing their finished dose pharmaceuticals from API suppliers. The drug developers combine the API with inactive ingredients and process the drugs into their final dosage form. The API for a brand drug is typically the same as the API for its generic equivalent.

46. To sell an API in the United States, the API supplier typically needs to submit a DMF with the FDA. The DMF provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API. To use an API for a specific drug, a developer must reference the API supplier’s DMF in its application with the FDA. More than one developer can reference the DMF of the same API supplier. As part of its review of an NDA or ANDA, the FDA performs a complete review of the technical information contained in the DMF, including, among other things, inspecting the facilities described in the DMF.

47. The entire process, from API development to FDA approval for use of that API supplier’s DMF in support of an NDA or ANDA, ordinarily takes more than a year to complete and can extend to as long as three years.

¹ U.S. Dep’t of Health and Hum. Servs., Prescription Drugs: Innovation, Spending, and Patient Access, at 8 (2016).

48. If a drug developer wants or needs to change its API supplier for a drug prior to approval of its pending ANDA, it must file an amendment to its pending application requesting the withdrawal of the primary API supplier with information on the new supplier. The FDA will review all specifications and data for the new source, and this process is lengthy and can take years before approval. If, however, the change to the API supplier occurs after the approval of the ANDA, the drug developer must submit to the FDA a Prior Approval Supplement (“PAS”). The FDA is required to approve the change before distribution of the drug product can be accomplished using the new API supplier, but this process will typically take less time than filing an ANDA amendment.

49. Generic drug developers often use API from suppliers that already have a DMF on file with the FDA, which allows the developers to reference that DMF in their ANDA. Partnering with API suppliers that do not have a DMF on file with the FDA is drastically more resource- and time-intensive as well as costly, and approval is far less certain.

50. Generally, because of the significant investment involved in securing an ANDA, it is unusual and contrary to industry practice for an API supplier to support the generic developer’s ANDA filing by providing a LOA referencing its DMF unless that API supplier intends to support that developer’s commercial launch of the generic.

II. LAUNCH OF CLOMID®

51. Clomid® is the brand name for the clomiphene citrate drug product marketed by Cosette. The API for the drug is clomiphene citrate, a selective estrogen receptor modulator.

52. In 1967, the FDA approved an NDA for Sanofi Aventis US LLC’s (“Sanofi”) brand clomiphene citrate product. Sanofi subsequently merged with Hoechst Marion Roussel, Inc. (“Hoechst”). In 1999, the FDA approved Par’s ANDA for a generic clomiphene citrate product as a therapeutic equivalent to Hoechst’s brand clomiphene citrate tablets. Cosette acquired Par’s

clomiphene citrate product in September 2022, began marketing it as “Clomid” in October 2022, and secured a registered trademark for the once-generic product in November 2022. The Hoechst product was discontinued some time prior to 2022, leaving the Par product acquired by Cosette marketed as Clomid® as the only clomiphene citrate product available to patients in the United States.

53. As part of its scheme to prevent competitive entry into the clomiphene citrate market and raise prices to supracompetitive levels, Cosette increased prices by more than 1,000 percent. More specifically, until September 2022, Par’s 10-pack of clomiphene citrate typically sold for under \$6 and its 30-pack typically sold for under \$14. Starting in October 2022, Cosette sold the same product at \$38-\$63 for the 10-pack and \$115-\$194 for the 30-pack. In other words, within a few months’ time, Cosette increase prices by more than 1,000 percent. There are no other generic clomiphene citrate tablets on the market and in the absence of generic competition, consumers are forced to pay these supracompetitive prices, for a product that has been marketed and sold in the United States as a generic for decades.

III. APPCO’S DEVELOPMENT OF CLOMIPHENE CITRATE

54. Appco began developing its generic clomiphene citrate product several years ago, culminating in its filing of an ANDA with the FDA on March 9, 2023.

55. During this time, Appco purchased or was given samples of FIS’s clomiphene citrate for the purposes of supporting Appco’s ANDA. At Appco’s request, in September 2022, FIS filed a LOA with the FDA referencing its DMF for clomiphene citrate API in support of Appco’s ANDA.

56. FIS cooperated with Appco throughout the development of its clomiphene citrate product. Plaintiffs thus had every reason to believe that FIS would continue to work cooperatively

with Plaintiffs until the ANDA was approved and their generic clomiphene citrate product was launched.

57. On September 22, 2021, Appco asked the FDA to designate clomiphene citrate tablets as a CGT product due to the lack of generic competition, and the FDA granted that designation on November 19, 2021.

58. On April 17, 2023, the FDA provided a goal approval date for Appco's generic clomiphene citrate product of January 9, 2024.

59. On information and belief, no other pharmaceutical company has launched a new generic clomiphene citrate product or filed an ANDA for generic clomiphene citrate tablets.

60. On February 20, 2014, as amended December 30, 2021, Appco and Rising entered into a Master Collaboration Agreement ("MCA"), whereby Appco appointed and granted to Rising the exclusive right and license to market, distribute, offer for sale and sell certain products, including clomiphene citrate tablets, in the United States during the term of the license. All products sold by Rising under the MCA bear the Rising trademark, trade dress, and applicable Rising National Drug Code and labeler code. The parties agreed to split net profits from the sale of pharmaceuticals covered by the MCA in accordance with an agreed profit-sharing percentage. Pursuant to the MCA, Rising also pays for fifty percent of the development costs incurred by Appco for developing the product and is therefore a co-developer.

IV. API FOR CLOMIPHENE CITRATE

61. The API for Clomid[®] is clomiphene citrate. FIS had been supplying API in support of Appco's development of generic clomiphene citrate tablets.

62. Prior to January 2023, Appco purchased FIS's API through FIS's U.S. market distributor SST Corporation based in New Jersey. Such orders were fulfilled.

63. On January 1, 2023, FIS began to deal with Plaintiffs directly through FIS's North American contacts. Plaintiffs expressed urgency in obtaining a response from FIS due to the upcoming launch date, but FIS provided vague updates and promises about providing more information soon.

64. An in-person meeting was held in March 2023 among the parties, but still FIS provided no more definitive response on the future availability of clomiphene citrate API and refused to support inquiries relating to the ANDA.

V. DEFENDANTS' EXCLUSIVE DEALING ARRANGEMENT

65. On April 18, 2023, FIS informed Appco that it would be "impossible" for FIS to supply Appco with clomiphene citrate API in 2023 to support FDA approval for launch on the goal date of January 9, 2024.

66. In separate communications around this time, FIS also informed Plaintiffs that FIS had entered into an exclusive dealing arrangement to sell the entirety of FIS's clomiphene citrate API—approximately one ton—to a single drug manufacturer, which is known to be Cosette.

67. Based on these communications with FIS, Plaintiffs understand that Cosette offered to share with FIS a financial incentive of some kind from what Cosette earns on sales of Clomid[®], thus providing incentive to FIS to refuse to deal with Plaintiffs. The more sales Cosette makes on Clomid[®] sales, the more FIS earns.

68. Not surprisingly, therefore, FIS has refused to commit to supplying Appco with *any* clomiphene citrate API to support Plaintiffs' commercial launch for years into the future.

69. FIS has also failed to support Plaintiffs' efforts in development and securing regulatory approval of the ANDA for generic clomiphene citrate tablets. Specifically, FIS has refused to provide Appco with even the limited quantities of clomiphene citrate API sufficient for Appco to conduct stability testing to establish the shelf-life and storage instructions of its

clomiphene citrate product or otherwise be able to provide the information necessary to respond to FDA inquiries.

70. Plaintiffs have been unable to find an alternative API supplier. Only three other API suppliers have DMFs for clomiphene citrate API. Of those three, two no longer sell clomiphene citrate API in the United States and one produces insufficient clomiphene citrate to support the commercial launch of Plaintiffs' clomiphene citrate tablets.

71. Moreover, even if an alternate API supplier were available, any change in API supplier in Appco's ANDA prior to approval will cause substantial delay in the approval of the ANDA. In effect, Appco will be required to redevelop the product using the API of the second supplier, conduct new stability studies, and resubmit its ANDA to the FDA. The entire process could delay launch by two to three years from the withdrawal of the original ANDA.

VI. DEFENDANTS' CONDUCT IS CONTRARY TO INDUSTRY PRACTICE, HAS NO LEGITIMATE JUSTIFICATION, AND CAN BE EXPLAINED ONLY AS AN ANTICOMPETITIVE STRATEGY

72. As a matter of industry practice and custom, an API supplier does not typically authorize a drug developer to include the supplier's DMF as part of an ANDA submission to the FDA unless the API supplier plans to support the drug developer during the commercial launch of its product. FIS authorized Appco to use FIS's DMF and indicated that FIS would support the launch of Plaintiffs' generic clomiphene citrate tablets. FIS only changed course once it agreed with Cosette to enter into an unlawful exclusive dealing and profit-share arrangement tying up access to clomiphene citrate API for years.

73. There is no other reasonable explanation for FIS's conduct. Before FIS finalized its deal with Cosette, it knew that Plaintiffs wanted to purchase sufficient quantities of clomiphene citrate API to support Plaintiffs' commercial launch. If FIS desired to ensure that it could sell its entire supply of clomiphene citrate API, then it would have sought assurances from Plaintiffs. If

FIS wanted to obtain the highest price, then it could have asked for competing bids from buyers. But FIS did not seek a competing bid or assurances from Plaintiffs. Instead, it was lured into an unlawful arrangement by securing its share of supracompetitive prices afforded by the monopoly Cosette offered through the exclusion of Plaintiffs.

74. Absent Defendants’ agreement to lock out Plaintiffs’ supply of API, Plaintiffs would have been able to enter the market and compete for a portion of Cosette’s customers at significantly lower prices. Rather than allow those customers to benefit from that competition and reduced generic pricing, Defendants’ conduct ensures that Cosette is the only manufacturer selling clomiphene citrate tablets in the U.S. market—exactly what Cosette had planned.

VII. COSETTE’S CONDUCT HARMS PLAINTIFFS

75. Appco has successfully developed generic clomiphene citrate tablets and on good faith and belief would have received regulatory approval to market its product on or around January 9, 2024, but without FIS’s API, Plaintiffs were unable to obtain FDA approval for their clomiphene citrate generic product. Rising intends and is fully prepared to commercially launch Appco’s generic clomiphene citrate product as soon as possible, which Plaintiffs expected would have been in January 2024 but for Defendants’ anticompetitive conduct. Defendants’ conduct has delayed Plaintiffs’ launch of its generic clomiphene citrate product, resulting in significantly higher prices to patients and payors and potentially years of lost sales to Plaintiffs.

MONOPOLY POWER AND RELEVANT MARKET

76. Since September 2022, Cosette has maintained monopoly power in the market for FDA-approved clomiphene citrate tablets, which includes Cosette’s Clomid® product (“Clomiphene Citrate Market”).

77. Cosette’s monopoly power includes the ability to control prices and exclude competitors.

78. Cosette has been able to profitably raise prices in the Clomiphene Citrate Market. A small but significant and non-transitory price increase in the price of Clomid[®] has not resulted in a significant loss of sales, nor would a future small but significant and non-transitory price increase result in lost sales. In fact, despite Cosette's more than 1,000 percent price increase since acquiring the clomiphene citrate product, sales of Clomid[®] have not markedly decreased.

79. In addition to direct evidence of monopoly power, indirect evidence also establishes Cosette's monopoly power. The Clomiphene Citrate Market exhibits high barriers to entry, including the costs of developing the product, regulatory requirements, and the high cost of entry and expansion.

80. Cosette controls 100 percent of the Clomiphene Citrate Market. No other company sells clomiphene citrate tablets, and absent relief from this Court, Plaintiffs will not be able to enter the Clomiphene Citrate Market for years to come.

81. The Clomiphene Citrate Market is not reasonably interchangeable with any other market except for AB-rated generic versions of Clomid[®].

82. Clomid[®] is the only product in the Clomiphene Citrate Market currently being marketed and sold in the United States. The existence of other FDA-approved treatments for ovulatory dysfunction has not significantly constrained Cosette, as Cosette successfully increased the price of Clomid[®] by more than 1,000 percent since acquiring the generic drug.

83. Given the exorbitant increase in price without a marked change in demand over the passage of time, there are no other infertility treatments that act as a constraint on the price of Clomid[®].

84. Manufacturers differentiate brand products like Clomid[®] based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally

price-insensitive when prescribing and taking prescription drugs like Clomid[®]. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Clomid[®].

85. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, prescribing decisions for prescription drugs are made by the prescriber, not consumers of these products.

86. FIS maintains monopoly power in the market for FDA-approved API used in the manufacture of products in the Clomiphene Citrate Market. FIS is the only current manufacturer of clomiphene citrate API capable of supplying the product at levels sufficient to maintain sales of clomiphene citrate in the United States. Therefore, FIS has nearly 100 percent of the market for sales of clomiphene citrate API.

87. The United States and its territories are the relevant geographic market.

ANTITRUST IMPACT

88. Cosette's anticompetitive strategy to maintain its monopoly in the Clomiphene Citrate Market through its exclusive agreement with FIS, unless remedied, will deny consumers the benefits of generic competition for Clomid[®] contemplated by the Hatch-Waxman Act. Cosette illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field.

89. Upon information and belief, Cosette has an exclusive agreement with FIS providing that if FIS sells all its clomiphene citrate API to Cosette, Cosette will provide FIS with a share of the supracompetitive profits Cosette is able to obtain by locking out all competitive entry in the Clomiphene Citrate Market.

90. Defendants' anticompetitive strategy to restrain trade by boycotting Plaintiffs, unless remedied, will deny consumers the benefits of generic competition for Clomid[®] contemplated by the Hatch-Waxman Act.

91. Defendants' anticompetitive conduct, unless remedied, will achieve Cosette's purpose of preventing and delaying generic competition to Cosette's Clomid[®] product. Through this anticompetitive agreement, Defendants have effectively foreclosed the entire supply for clomiphene citrate API. The lack of API supply will delay Plaintiffs and any other ANDA filers from launching their generic clomiphene citrate tablets even though there are no legal or regulatory hurdles preventing launch. This delay in competition is exactly what Defendants intend to cause through their unlawful conduct. During these periods of delay, consumers will be deprived of lower-priced generic clomiphene citrate drug tablets and will be forced to pay higher prices for a generic drug that has been on the market for more than 50 years.

92. Defendants' anticompetitive conduct has had a direct, substantial, and adverse effect on Plaintiffs and competition generally by monopolizing and maintaining Cosette's monopoly power, artificially creating barriers to entry, and foreclosing competition in the Clomiphene Citrate Market. But for Defendants' anticompetitive agreement, Plaintiffs would have obtained supply of clomiphene citrate API from FIS and would have been able to launch generic clomiphene citrate tablets upon receiving FDA approval as expected on or around January 9, 2024. However, because of Defendants' conduct, Plaintiffs' launch has been indefinitely delayed.

93. Defendants' anticompetitive conduct will impede the sale of generic clomiphene citrate tablets, and, thus, unless constrained by this Court, will allow Cosette to maintain and extend its monopoly power in the relevant market and to sell Clomid[®] at artificially inflated monopoly prices.

94. This conduct has harmed the competitive process and will allow Cosette to perpetuate supracompetitive prices against retailers, wholesalers, insurers, governments, and consumers. But for Defendants' anticompetitive conduct, patients and others throughout the distribution chain would enjoy the benefits of lower-priced generic competition. Instead, as a result of Defendants' strategies to prevent generic entry, all consumers and payors will continue to be forced to pay monopoly prices for Clomid[®]. The impact of Defendants' conduct is felt throughout the healthcare industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

95. There are no valid procompetitive business justifications for Defendants' anticompetitive conduct, and to the extent Defendants offer one, it is pretextual and not cognizable, and any procompetitive benefits of Defendants' conduct do not outweigh the anticompetitive harms.

COUNT I

SHERMAN ACT SECTION 1 – RESTRAINT OF TRADE

96. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

97. The Clomiphene Citrate Market in the United States is the relevant market. Cosette has market power in the relevant market.

98. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Cosette and FIS have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining, and/or agreeing to restrain trade in the Clomiphene Citrate Market through an unlawful exclusive dealing and profit-sharing arrangement designed to enable Cosette to raise and maintain prices significantly.

99. Through the foregoing acts, Defendants unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. §1, have acted pursuant to a contract, combination, or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Clomiphene Citrate Market.

100. Defendants knowingly and intentionally entered into an exclusive dealing and profit-sharing arrangement designed to prevent Plaintiffs from entering the Clomiphene Citrate Market and unlawfully delay the launch of an AB-rated generic version of Clomid®.

101. This agreement constitutes a contract, combination, and conspiracy that substantially, unreasonably, and unduly restrains trade in the relevant market, thereby harming Plaintiffs.

102. Defendants' conduct has no procompetitive, legitimate business justification and is not reasonably necessary to accomplish any procompetitive objective. Defendants' conduct can be explained only by anticompetitive motives and a specific intent to foreclose competition in the Clomiphene Citrate Market. Any justification that may exist does not outweigh the substantive anticompetitive effect of Defendants' conduct.

103. As a result of Defendants' unlawful contract, combination, and conspiracy, Plaintiffs will suffer injury to their business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

104. Defendants' unlawful contract, combination, and conspiracy as set forth above will have the following effects, amongst others:

- Competition in the manufacture and sale of generic clomiphene citrate tablets will be restrained, suppressed, and eliminated;

- Purchasers of clomiphene citrate tablets will be deprived of the benefits of free and open competition, and the availability of lower-cost generic clomiphene citrate tablets; and
- Cosette will continue to sell Clomid[®] at artificially high and noncompetitive price levels.

105. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

106. Defendants' anticompetitive conduct has directly and proximately caused injury to Plaintiffs' business and property, as set forth above, for which Defendants are jointly and severally liable. Plaintiffs' injury is the type the antitrust laws are intended to prevent and thus constitutes antitrust injury.

107. Defendants' unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Plaintiffs will suffer irreparable injury for which they are without an adequate remedy at law.

108. Plaintiffs are entitled to a judgment that Defendants have violated Section 1 of the Sherman Act; to damages they suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to their costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT II

SHERMAN ACT SECTION 2 – MONOPOLIZATION AND ATTEMPT TO MONOPOLIZE AS TO DEFENDANT COSETTE

109. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

110. The Clomiphene Citrate Market in the United States is the relevant market.

111. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Cosette has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolization and/or attempting to monopolize the Clomiphene Citrate Market.

112. Through the foregoing acts, Cosette unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. §2, has used, is using and, if not restrained by this Court, will continue to use, its power in the Clomiphene Citrate Market to monopolize and/or attempt to monopolize the Clomiphene Citrate Market.

113. Cosette possesses monopoly power in the Clomiphene Citrate Market by virtue of its 100 percent share of the Clomiphene Citrate Market. Using this monopoly power, Cosette was able to increase prices by more than 1,000 percent. The Clomiphene Citrate Market is also characterized by high barriers to entry.

114. Cosette knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Clomid[®], and thus to willfully maintain its monopoly power. Specifically, Cosette entered into an exclusive dealing and profit-sharing arrangement with the only viable U.S. supplier of clomiphene citrate API, knowing this would prevent the launch of any AB-rated generic versions of Clomid[®]. Upon information and belief, this exclusive arrangement provided Cosette with complete control over FIS's supply of clomiphene citrate API in the United States market, which enables Cosette to raise and maintain its prices at significantly increased levels and to deny competitors, including Plaintiffs, access to this essential ingredient for producing generic clomiphene citrate tablets.

115. Cosette engaged in this conduct with the specific intent to monopolize the Clomiphene Citrate Market.

116. Alternatively, Cosette has a dangerous probability of acquiring a monopoly in the Clomiphene Citrate Market by means of its unlawful conduct, as shown by the fact that Rising's launch of its generic clomiphene citrate product, absent relief by this Court, will be indefinitely delayed.

117. Cosette's conduct has no procompetitive, legitimate business justification. Cosette's conduct can be explained only by anticompetitive motives and a specific intent to foreclose competition in the Clomiphene Citrate Market.

118. To the extent there are legitimate business justifications for Cosette's exclusionary conduct, Cosette's anticompetitive conduct is not necessary to serve those justifications.

119. By its conduct, Cosette intentionally and wrongfully attempted to maintain monopoly power in the Clomiphene Citrate Market in violation of Section 2 of the Sherman Act. As a result of Cosette's unlawful monopolization and/or attempted monopolization, Plaintiffs will suffer injury to their business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

120. Cosette's unlawful conduct as set forth above will have the following effects, amongst others:

- Competition in the manufacture and sale of generic clomiphene citrate will be restrained, suppressed, and/or eliminated;
- Purchasers of clomiphene citrate will be deprived of the benefits of free and open competition, and the availability of a lower-cost generic clomiphene citrate product; and
- Cosette will continue to sell Clomid[®] at artificially high and noncompetitive price levels.

121. Cosette's conduct occurred in, and has had a substantial effect on, interstate commerce.

122. Cosette's anticompetitive and exclusionary conduct has directly and proximately caused injury to Plaintiffs' business and property, as set forth above. Plaintiffs' injuries are the type the antitrust laws are intended to prevent and thus constitutes antitrust injury.

123. Cosette's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Plaintiffs will suffer irreparable injury for which Plaintiffs are without an adequate remedy at law.

124. Plaintiffs are entitled to a judgment that Cosette has violated Section 2 of the Sherman Act; to damages they suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to their costs and attorneys' fees; and to an injunction restraining Cosette's continued violations.

COUNT III

SHERMAN ACT SECTION 2 – CONSPIRACY TO MONOPOLIZE

125. Plaintiffs repeat each and every allegation of the preceding paragraphs as if set forth fully herein.

126. Defendants conspired to act together to obtain monopoly power for Cosette in the Clomiphene Citrate Market.

127. Cosette acted with a specific intent to monopolize, and to eliminate competition in, the Clomiphene Citrate Market. Cosette devised and implemented a scheme to raise and maintain the price for Clomid[®] by locking up the supply of clomiphene citrate API, the essential ingredient for the manufacture of clomiphene citrate tablets. Each of the co-conspirators acted with the specific intent that Cosette obtain and maintain monopoly power in the Clomiphene Citrate Market, and through their exclusive dealing and profit-sharing arrangement and the resulting

higher prices, the co-conspirators each have profited and will continue to profit significantly from their conspiracy.

128. In furtherance of their conspiracy, Defendants entered into an exclusive dealing and profit-sharing arrangement whereby Cosette obtained the exclusive rights to all of FIS's supply of clomiphene citrate API. This had the purpose and effect of denying to Cosette's competitors in the Clomiphene Citrate Market the supply of an essential raw material. Defendants were aware that there were no adequate alternate sources of available clomiphene citrate API for use in the United States.

129. Defendants' conspiracy to monopolize the Clomiphene Citrate Market had the effect of harming the competitive process. By entering into the exclusive dealing and profit-sharing arrangement, Defendants prevented Plaintiffs from obtaining clomiphene citrate API, enabling Cosette to significantly raise and maintain prices for Clomid[®] and acquire and/or maintain monopoly power in the Clomiphene Citrate Market.

130. Defendants' conduct has no procompetitive, legitimate business justification and is not reasonably necessary to accomplish any procompetitive objective. Defendants' conduct can be explained only by anticompetitive motives and a specific intent to foreclose competition in the Clomiphene Citrate Market. Any justification that may exist does not outweigh the substantive anticompetitive effect of Defendants' conduct.

131. As a result of Defendants' unlawful contract, combination, and conspiracy, Plaintiffs will suffer injury to their business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

132. Defendants' unlawful conduct as set forth above will have the following effects, amongst others:

- Competition in the manufacture and sale of generic clomiphene citrate tablets will be restrained, suppressed, and eliminated;
- Purchasers of clomiphene citrate tablets will be deprived of the benefits of free and open competition, and the availability of a lower-cost generic clomiphene citrate tablet; and
- Cosette will continue to sell Clomid[®] at artificially high and noncompetitive price levels.

133. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

134. Defendants' anticompetitive conduct has directly and proximately caused injury to Plaintiffs' business and property, as set forth above, for which Defendants are jointly and severally liable. Plaintiffs' injury is the type the antitrust laws are intended to prevent and thus constitutes antitrust injury.

135. Defendants' unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Plaintiffs will suffer irreparable injury for which they are without an adequate remedy at law.

136. Plaintiffs are entitled to a judgment that Defendants have violated Section 1 of the Sherman Act; to damages they suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to their costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT IV

**NEW JERSEY ANTITRUST ACT SECTION 56:9-4 – MONOPOLIZATION,
ATTEMPT TO MONOPOLIZE, AND CONSPIRACY TO MONOPOLIZE**

137. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

138. This claim arises under the New Jersey Antitrust Act § 56:9-4 and seeks a judgment that Defendants have violated the New Jersey Antitrust Act, by monopolization, attempted monopolization, and/or conspiracy to monopolize the Clomiphene Citrate Market within the State of New Jersey.

139. Section 56:9-4 of the New Jersey Antitrust Act makes it unlawful for any person to monopolize, attempt to monopolize, or combine or conspire to monopolize trade or commerce in any relevant market within the State.

140. Through the foregoing acts, Defendants unlawfully and in violation of New Jersey Antitrust Act § 56:9-4, have used, are using and, if not restrained by this Court, will continue to use, their power in the Clomiphene Citrate Market to monopolize, attempt to monopolize, and/or conspire to monopolize the Clomiphene Citrate Market.

141. Cosette possesses monopoly power in the Clomiphene Citrate Market by virtue of its 100 percent share of the Clomiphene Citrate Market. Using this monopoly power, Cosette was able to increase prices by more than 1,000 percent. The Clomiphene Citrate Market is also characterized by high barriers to entry.

142. Defendants knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Clomid[®] and thus to willfully maintain Cosette's monopoly power. Specifically, Cosette entered into an exclusive dealing and profit-sharing arrangement with FIS that locked up the supplies of clomiphene citrate

API from FIS, the only viable supplier, knowing this would prevent the launch of any AB-rated generic versions of Clomid®. Upon information and belief, this exclusive arrangement provided Cosette with complete control over FIS's supply of clomiphene citrate API, which enables Cosette to raise and maintain its prices at significantly increased levels and to deny competitors, including Plaintiffs, access to this essential ingredient for producing generic clomiphene citrate tablets.

143. Defendants engaged in this conduct with the specific intent to monopolize the Clomiphene Citrate Market.

144. Alternatively, Cosette has a dangerous probability of acquiring a monopoly in the Clomiphene Citrate Market by means of its unlawful conduct, as shown by the fact that Rising's launch of its generic clomiphene citrate product, absent relief by this Court, will be indefinitely delayed.

145. Defendants' conduct has no procompetitive, legitimate business justification. Defendants' conduct can be explained only by anticompetitive motives and a specific intent to foreclose competition in the Clomiphene Citrate Market.

146. To the extent there are legitimate business justifications for Defendants' exclusionary conduct, Defendants' anticompetitive conduct is not necessary to serve those justifications.

147. By their conduct, Defendants intentionally and wrongfully attempted to maintain Cosette's monopoly power in the Clomiphene Citrate Market in violation of the New Jersey Antitrust Act § 56:9-4. As a result of Defendants' unlawful monopolization, attempt to monopolize, and/or conspiracy to monopolize, Plaintiffs will suffer injury to their business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

148. Defendants unlawful conduct as set forth above will have the following effects, amongst others:

- Competition in the manufacture and sale of clomiphene citrate will be restrained, suppressed, and eliminated;
- Purchasers of clomiphene citrate will be deprived of the benefits of free and open competition, and the availability of a lower-cost generic clomiphene citrate product; and
- Cosette will continue to sell its Clomid® at artificially high and noncompetitive price levels.

149. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce and specifically commerce within the State of New Jersey.

150. Defendants' anticompetitive and exclusionary conduct has directly and proximately caused injury to Plaintiffs' business and property, as set forth above. Plaintiffs' injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

151. Defendants' unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Plaintiffs will suffer irreparable injury for which Plaintiffs are without an adequate remedy at law.

152. Plaintiffs are entitled to a judgment that Defendants have violated Section 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT V

NEW JERSEY ANTITRUST ACT SECTION 56:9-3 – RESTRAINT OF TRADE

153. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

154. This claim arises under the New Jersey Antitrust Act § 56:9-3 and seeks a judgment that Defendants have violated this Act, by conspiring, combining, and/or agreeing to restrain trade in the Clomiphene Citrate Market within the State of New Jersey through an unlawful exclusive dealing and profit-sharing arrangement designed to enable Cosette to raise and maintain prices significantly.

155. Cosette has market power in the Clomiphene Citrate Market.

156. Through the foregoing acts, Defendants' unlawfully and in violation of Section 56:9-3 of the New Jersey Antitrust Act, have acted pursuant to a contract, combination, or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Clomiphene Citrate Market.

157. Defendants knowingly and intentionally entered into an exclusive dealing and profit-sharing arrangement designed to prevent Plaintiffs from entering the Clomiphene Citrate Market and unlawfully delay the launch of an AB-rated generic version of Clomid®.

158. This agreement constitutes a contract, combination, and conspiracy that substantially, unreasonably, and unduly restrains trade in the relevant market, thereby harming Plaintiffs.

159. Defendants' conduct has no procompetitive, legitimate business justification. Defendants' conduct can be explained only by anticompetitive motives and a specific intent to foreclose competition in the Clomiphene Citrate Market. Any justification that may exist does not outweigh the substantive anticompetitive effect of Defendants' conduct.

160. As a result of Defendants' unlawful contract, combination, and conspiracy, Plaintiffs will suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

161. Defendants' unlawful contract, combination, and conspiracy as set forth above will have the following effects, amongst others:

- Competition in the manufacture and sale of clomiphene citrate tablets will be restrained, suppressed, and eliminated;
- Purchasers of clomiphene citrate tablets will be deprived of the benefits of free and open competition, and the availability of a lower-cost generic clomiphene citrate tablet; and
- Cosette will continue to sell its Clomid® at artificially high and noncompetitive price levels.

162. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce and specifically commerce in the State of New Jersey.

163. Defendants' anticompetitive conduct has directly and proximately caused injury to Plaintiffs' business and property, as set forth above, for which Defendants are jointly and severally liable. Plaintiffs' injury is the type the antitrust laws are intended to prevent and thus constitutes an antitrust injury.

164. Defendants' unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Plaintiffs will suffer irreparable injury for which Rising is without an adequate remedy at law.

165. Plaintiffs are entitled to a judgment that Defendants violated Section 56:9-3 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in

accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT VI

PROMISSORY ESTOPPEL AS TO DEFENDANT FIS

166. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

167. FIS made clear and definite promises and representations to Plaintiffs that FIS would fulfill Plaintiffs' requests for clomiphene citrate API when made and provide regulatory support in furtherance of securing the FDA's approval of Appco's ANDA.

168. FIS expected or should have expected that the promises made by it would be relied upon by Plaintiffs.

169. Plaintiffs reasonably relied on these promises as it was usual and customary to do in the industry and given the parties' past dealings.

170. As detailed above, up until January 2023, FIS fulfilled (through its distributor at the time SST Corporation) Plaintiffs' requests for clomiphene citrate API.

171. Prior to January 2023, upon Plaintiffs' requests, FIS also provided regulatory support in furtherance of securing approval for Appco's ANDA. Particularly, on or about September 19, 2022, FIS submitted to the FDA a LOA permitting Appco to incorporate by reference FIS's DMF for clomiphene citrate into Appco's ANDA for clomiphene citrate tablets and authorized the FDA to review the referenced DMF when considering any application Appco filed for the specified product.

172. Upon Defendants' request, which Defendants did in reliance that FIS would be its API supplier for its clomiphene citrate product, on or about November 19, 2021, the FDA granted

CGT designation to Defendants' ANDA for clomiphene citrate which entitled Plaintiffs to an 18-month exclusivity period. FIS was aware of this designation, making time of the essence.

173. On or about December 2022, Plaintiffs requested additional clomiphene citrate API from FIS as well as its regulatory assistance in securing FDA approval of the ANDA. FIS provided unspecified delays in response.

174. In further reliance that FIS would be its API supplier for its clomiphene citrate product as indicated by the LOA and prior dealings, on or about March 9, 2023, Appco submitted an ANDA to the FDA to obtain the right to market and sell clomiphene citrate tablets, which included reference to FIS's DMF.

175. Plaintiffs later learned that FIS had entered into an exclusive dealing and profit-sharing arrangement with Cosette to exclude Plaintiffs' requests for API supplies and regulatory support.

176. FIS also failed to disclose to Plaintiffs its dealings with Cosette which were in direct conflict with its promises and representations to Plaintiffs.

177. Plaintiffs' reliance on FIS's promises and representations caused Plaintiffs to suffer a definite and substantial detriment, namely reliance on FIS's supply of API in applying for an exclusivity period, submitting an ANDA with reference to FIS's DMF as API supplier, depending on FIS's LOA, and relying on FIS for the planned launch of a generic clomiphene citrate product.

178. Had FIS fulfilled its promises, Plaintiffs would have been in position to commercially launch the generic clomiphene citrate product in January 2024.

179. Further, Plaintiffs have expended monies and other resources relying on FIS's promises as the API supplier to secure FDA approval of Appco's ANDA.

180. Plaintiffs are entitled to a judgment that FIS has breached its promises to Plaintiffs; to damages it suffered as a result of that breach, plus interest; to its costs and attorneys' fees; and to an injunction restraining FIS's continued violations.

COUNT VII

TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC BENEFIT AS TO DEFENDANT COSETTE

181. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

182. Plaintiffs had a reasonable expectation of prospective economic benefit, particularly sufficient supply of clomiphene citrate API and regulatory assistance from FIS.

183. Upon information and belief, Cosette was aware of Appco's ANDA and CGT designation with the FDA.

184. Upon information and belief, Cosette was aware that FIS was Plaintiffs' clomiphene citrate API supplier, and that FIS was providing regulatory support in furtherance of securing FDA approval of Appco's ANDA.

185. Cosette has intentionally and maliciously interfered with Plaintiffs' relationship with FIS and Plaintiffs' prospective economic benefits of that relationship.

186. Cosette took actions or conspired with others to take actions to prevent Plaintiffs from securing clomiphene citrate API from FIS, bar FIS from providing regulatory support in furtherance of Plaintiffs' securing FDA approval of Appco's ANDA, as well as prevent Plaintiffs from securing an approved ANDA from the FDA, and frustrating Plaintiffs' commercial launch of its generic clomiphene citrate product. Upon information and belief, Cosette's agreement with FIS has prevented FIS from supplying further API to Plaintiffs.

187. Plaintiffs also have a reasonable expectation of prospective economic benefit from selling its generic clomiphene citrate product to third parties – distributors, pharmacies, and patients – who would purchase Plaintiffs’ product at a greatly reduced price instead of Cosette’s Clomid®.

188. But for Cosette’s interference, there was a reasonable probability that Plaintiffs would have received the prospective economic benefit of its dealings with FIS as well as that Plaintiffs reasonably expect to receive from sales of its generic product to third parties.

189. Cosette’s tortious interference has directly and proximately caused injury to Plaintiffs, including lost profits and business opportunities while Plaintiffs remain foreclosed from launching a generic clomiphene citrate product due to Cosette’s actions.

190. Plaintiffs are entitled to a judgment that Cosette has tortiously interfered with Plaintiffs’ contractual relationships and prospective business opportunities; to damages it suffered as a result of that interference, plus interest; to its costs and attorneys’ fees; and to an injunction restraining Cosette’s continued violations.

COUNT VIII

UNFAIR COMPETITION

191. Plaintiffs repeat and reallege each and every allegation of the preceding paragraphs as if set forth fully herein.

192. By reason of the foregoing unlawful, predatory, and anticompetitive acts as alleged herein, Defendants engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

193. As a result of the foregoing, Plaintiffs have been injured in their business and/or property and are entitled to damages, attorneys’ fees, costs of suit and other appropriate relief.

JURY DEMAND

194. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury as to all issues of right to a jury.

PRAYER FOR RELIEF

195. WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants as follows:

- a) Permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and New Jersey Antitrust Act §, 56:9-10, and other common law causes of action, restraining Defendants, its affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, from continuing, maintaining or renewing the conduct, contract, conspiracy, or combination alleged herein, or from engaging in any other conduct or entering into any other contract, conspiracy, or combination having a similar purpose or effect;
- b) Compensatory damages for Plaintiffs' lost sales of its generic clomiphene citrate product, and profits on those sales, that are caused by Defendants' conduct;
- c) Treble damages pursuant to 15 U.S.C. § 15 and New Jersey Antitrust Act § 56:9–12;
- d) Pre- and post-judgment interests as provided by law;
- e) An award of attorneys' fees and costs pursuant to 28 U.S.C. 15 and New Jersey Antitrust Act § 56:9–12; and
- f) Such other and further relief as the Court deems just and proper.

Dated: March 4, 2024
New York, NY

NORTON ROSE FULBRIGHT US LLP

By: /s/ Mayling C. Blanco
Robin D. Adelstein (subject to *pro hac*
admission)
Mayling C. Blanco
Kimberly A. Fetsick (subject to *pro hac*
admission)
NORTON ROSE FULBRIGHT US LLP
1301 Avenue of the Americas
New York, NY 10019-6022
Telephone: (212) 318-3000
Facsimile: (212) 408-5100
robin.adelstein@nortonrosefulbright.com
mayling.blanco@nortonrosefulbright.com
kimberly.fetsick@nortonrosefulbright.com

Mark Angland (subject to *pro hac* admission)
NORTON ROSE FULBRIGHT US LLP
799 9th Street NW Suite 1000
Washington, DC 20001
Telephone: (202) 662-4507
mark.angland@nortonrosefulbright.com

Attorneys for Plaintiffs Rising Pharma
Holdings, Inc. and Appco Pharma LLC